



**Regeneus Ltd**  
ABN 13 127 035 358

ASX Half-Year Report for 6 months to 31<sup>st</sup> December 2018

Provided to the ASX under Rule 4.2.A.3

This report is to be read in conjunction with the Annual Report for the year ended 30<sup>th</sup> June 2018 and any public announcements made during the reporting period, in accordance with the continuous disclosure requirements of the Australian Stock Exchange Listing Rules and the Corporations Act 2001.

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Results for announcement to the market

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Half-Year Report for the 6 months to 31<sup>st</sup> December 2018

Regeneus Ltd – ABN 13 127 035 358

## Reporting period

Report for the half-year ended 31<sup>st</sup> December 2018

Corresponding period is for the half-year ended 31<sup>st</sup> December 2017

## Results for announcement to the market

	Up / down	% Change		\$'000's
Revenues from ordinary activities	down	96%	to	(15)
Loss from ordinary activities after tax attributable to members	down	2%	to	(2,668)
Net loss from ordinary activities attributable to the members	down	2%	to	(2,668)
It is not proposed to pay any dividend				
Full details are in the attached accounts.				

## Net Tangible assets per security

The net tangible assets (liabilities) per security

31<sup>st</sup> December 2018 (1.5) cents

31<sup>st</sup> December 2017 2.6 cents

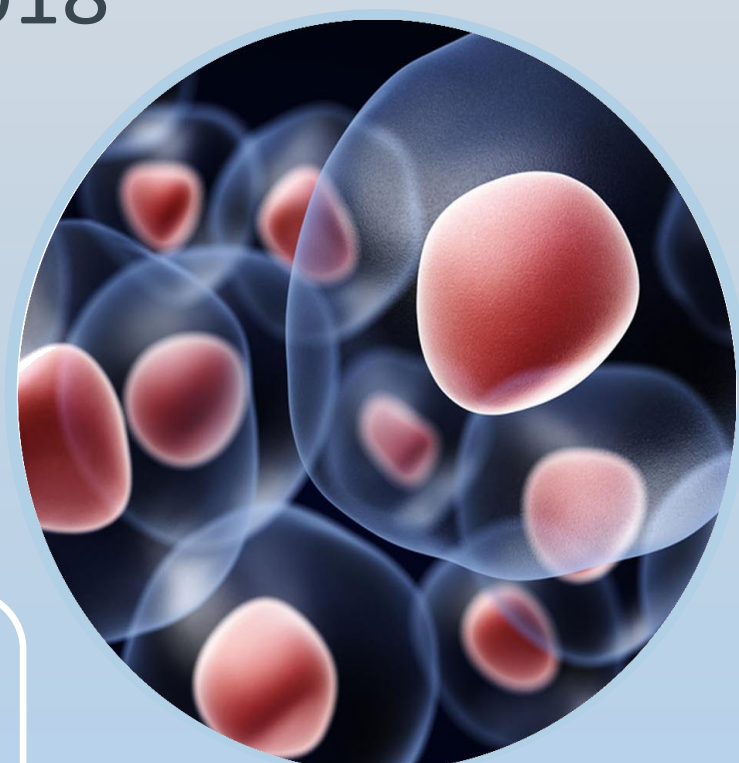
## Independent review of the financial information

The independent audit review is attached to the half-year financial statements.



# Half-Year Report

## 31<sup>st</sup> December 2018



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# 01 Directors' Report

Your Directors present their half-year report for Regeneus Ltd (Regeneus or the Company) and its controlled entities (the Group) for the half-year ended 31 December 2018, in order to comply with the provisions of the Corporations Act 2001. The Directors report the following information.

## 1. Directors

The following persons were Directors of Regeneus during the whole of the half-year and up to the date of this report, unless otherwise stated.

Name	Position
Dr Roger Aston	Non-executive Chairman, Chair of the Remuneration and Nominations Committee
Leo Lee <sup>1</sup>	CEO and Executive Director
John Martin <sup>2</sup>	Non-executive Director (previously CEO and Executive Director)
Professor Graham Vesey	CSO and Executive Director
Barry Sechos	Non-executive Director, Chair of the Audit and Risk Committee
Dr Glen Richards	Non-executive Director

<sup>1</sup> Leo Lee was appointed CEO on 23 January

<sup>2</sup> John Martin resigned as CEO on 23 January, remaining as a Non-executive Director

## 2. Review of operations

### Overview and strategy

Regeneus is an ASX-listed clinical-stage regenerative medicine company developing a portfolio of novel cell-based therapies targeting significant unmet medical needs in human and animal health, with an initial focus on osteoarthritis (OA), neuropathic pain and dermatology. The Company's product pipeline is underpinned by proprietary stem cell technologies.

Our strategy is to unlock value in our clinical-stage human pipeline products through developing novel and scalable technology product platforms underpinned by registered intellectual property; generating positive clinical data; and licensing to commercial partners at the optimal value inflection point. As these patented technologies have broad application, the Company has the opportunity to license the manufacturing and clinical development and commercialisation rights for a range of therapeutic indications in multiple territories, generating significant revenue streams.

### Human health

#### Progenza

Progenza is the Company's patented and scalable cell therapy technology platform that is being developed for the treatment of osteoarthritis and other musculoskeletal diseases. It also has the potential to be used for other inflammatory conditions that have limited treatment options.

#### Partnering Progenza in Japan

During the period, we made substantial progress on advancing discussions and due diligence with potential licensees for the initial clinical development and commercialisation licence of Progenza in Japan. While partnership discussions have taken longer than anticipated Regeneus remains confident of a successful commercial outcome that will maximise the value of the assets.

The granting of this licence will drive the Phase 2 trial of Progenza for osteoarthritis in Japan and take advantage of the accelerated approval pathway for regenerative medicine products in Japan. We believe it will also enhance our licensing opportunities for Progenza for osteoarthritis in other key territories.

#### Chronic pain research

Chronic pain is a symptom of osteoarthritis and Progenza's 'STEP trial', has shown promise in reducing pain for osteoarthritis sufferers.

Regeneus is part of a research consortium including University of NSW and University of Adelaide that has received an Australian Research Council (ARC) linkage grant to undertake research into the use of the Progenza and Sygenus technologies to relieve chronic pain. The investigations are being led by Professor Mark Hutchinson of the University of Adelaide and Professor Ewa Goldys of University of NSW.

The three year research project will seek to develop a better understanding of chronic pain and how stem cells and their secretions can be used to relieve chronic pain in animals and help lay the foundations for future human therapies.

# 01 Directors' Report

Regeneus has patents and patent applications on the use of stem cells for the treatment of neuropathic pain.

## **Sygenus – cell secretions technology**

Sygenus is the Company's patented and scalable cell secretions technology platform. It utilises the molecules including cytokines, growth factors and exosomes that are secreted by donor mesenchymal stem cells and secretions. These bioactive molecules are known to reduce pain and inflammation and encourage accelerated healing and repair.

## **RGSH4K – human cancer vaccine**

RGSH4K is a cancer vaccine technology that uses a patient's tumour to harness the body's own immune system against cancer cells. RGSH4K combines a patient's tumour proteins with a bacterial adjuvant for immune recognition.

On 30 July 2018, we announced the Phase 1 trial of the vaccine had met its endpoint of safety and tolerability and showed encouraging signs of immune stimulation in patients from each cohort as demonstrated by changes in cancer markers, immune cells and cytokines

The Principal Investigators of the trial are due to publish their findings, in a peer reviewed journal, at which time we will take the opportunity to open up licensing discussions with parties who have shown an interest in the cancer vaccine technology.

## **Animal health**

### **CryoShot - allogeneic stem cells for canine osteoarthritis**

CryoShot is the Company's cell therapy technology for the treatment of canine and equine osteoarthritis and other musculoskeletal diseases.

Over the last several years over 4,000 animals have been treated using CryoShot in field studies and recently a placebo-controlled trial was conducted at University of Pennsylvania School of Veterinary Medicine. Once the data from these activities has been finalised, the Company will explore the next steps including potentially the design of a pivotal US Food and Drug Administration (FDA) trial.

### **Kvax - trials of animal cancer vaccine**

Kvax is a canine cancer vaccine technology similar to RGSH4K.

A 45 dog double-blind placebo controlled trial of Kvax in combination with chemotherapy for the treatment of canine lymphoma is currently progressing. This trial builds upon the positive results from a Kvax trial for canine osteosarcoma which showed that Kvax was safe, tolerable and conferred increased progression free interval and survival compared to historically reported dogs with osteosarcoma treated with limb amputation only.

The Company continues to build up clinical data to support licensing opportunities for Kvax.

## **IP update**

Regeneus has in excess of 80 patents or patent applications across multiple patent families relating to its regenerative medicine development products.

In July 2018, we announced the United States Patent Office issued a notice of allowance for issuance of a key patent for composition, manufacture and use of Progenza for the treatment of a wide range of inflammatory conditions including osteoarthritis.

In October 2018 the European Patent Office issued notice of intention to grant European patent, providing coverage for the use of Progenza in up to 38 European member states, including the UK, Germany, France and Italy.

Then further extending our patent protection in December 2018 the Company was granted a Chinese Patent for biomarkers to monitor disease progression for stem cell therapy. The patent provides protection for the licensing the Company's Progenza allogeneic MSC therapeutics in China providing commercial rights in China until 2033. These patents will join corresponding patents in Australia, New Zealand and Japan.

# 01 Directors' Report

## 3. Financial results

### Operating results

The financial performance for the 6 months ending 31 December 2018 was a loss of \$2.7m which is broadly in line with the prior comparative period of 31 December 2017 of loss of \$2.7m. The key contributor to this reduction is the lower R&D expenditure and other cost containment activities pending the appointment of a Japanese licence partner offset by a foreign exchange expense relating to a contract liability recognised on initial adoption of AASB 15.

### Revenue and gross margin from continuing operations

There was no material revenue during the period. The prior comparable period included revenue of \$0.4m being licence fees for the use of the Group's technology locally.

### Other income

The Group's research and development activities are eligible expenditure under the Australian Government tax incentive.

The R&D tax incentive recognised in the Consolidated Statement of Profit or Loss for the period to 31 December 2018 is \$0.8m (31 December 2017: \$1.2m).

### Expenses from continuing operations

#### Research and Development

Expenditure on research in the half-year period to 31 December 2018 was \$1.3m compared to 31 December 2017 of \$2.1m.

Research expenditure includes costs associated with product development as well as clinical trials. The focus over the last year has included product development and trial activity particularly for the Progenza platform. Research expenditure has been maintained at lower levels than prior years as the focus has been on the clinical licensing of Progenza and the ongoing Japan development and technology transfer.

The current accounting policy, and to comply with the accounting standards, is that all costs incurred for research are fully expensed. This policy is being continually reviewed as products move toward licensing and commercialisation.

#### Corporate

Corporate expenses at \$1.6m is significantly down on the prior year of \$1.8m. This is reflective of active cost containment pending the appointment of a Japanese licence partner.

#### Occupancy

Occupancy expenditure at \$0.2m is the same as the prior year and reflects the costs associated with the corporate office in Sydney.

#### Finance

The 2018 finance expense includes costs associated with extending the Paddington St Finance Loan facility and the interest expense on this facility.

# 01 Directors' Report

## Cash flows

The net inflow for the period was \$52k compared to the prior corresponding period outflow 2017: \$763k.

	31 Dec 18 \$	31 Dec 17 \$	Movement \$
Cash flows from operating activities	(823,878)	(974,565)	150,687
Cash flows from investing activities	(3,690)	(102,275)	98,585
Cash flows from financing activities	880,000	313,650	566,350
<b>Net cash flows</b>	<b>52,432</b>	<b>(763,190)</b>	<b>815,622</b>

*Operating activities* – cash used in operating activities at \$824k was broadly in line with 31 December 2017 of \$975k. The lower cash outflow reflects several significant differences including increased costs of borrowing up \$119k, reduction in licence receipts of \$339k and R&D Tax Incentive receipt of \$251k offset by reductions in the level of R&D expenditure and operating activities which are down \$854k.

*Financing activities* – cash provided by financing activities is the draw down of the balance of the Paddington St Finance facility, as compared to the prior period which is the early repayment of loans to shareholders, provided at the time of the 2013 IPO.

### *Significant changes in state of affairs*

There were no significant changes in the Group's state of affairs during the first-half FY19.

### *Events subsequent to the end of the reporting date*

In the period since 31 December 2018 to the signing of the financial report, the following significant events have occurred:

On the 23 January, Leo Lee, formerly a non-executive Director was appointed to the position of Managing Director and CEO. John Martin resigned as CEO and will remain on the Board as a Non-executive Director.

On the 28 February 2019, the Company received loans from the Directors in total of \$2,500,000. Regeneus had previously considered funding from other sources and determined these Director loans were the most attractive commercial arrangement and entered into the necessary arrangement on arm's length terms. The loans are unsecured and repayable on the earlier of 2 March 2020 or 10 days after a capital raise sufficient to fund repayment of the loans of the Company and support the working capital requirements of the Company for the following 12 months, as reasonably determined by the Board of Directors.

Also, at that time Paddington St Finance amended the terms of its loan such that all interest from 1 October 2018 will be accrued. The accrued interest and principal will be repayable from the Group's R&D tax incentive receipts for 2019 unless the Group has raised more than \$6 million from either a capital raise or the sale, licensing or other disposal of any of the Group's assets. Where \$6 million has not been raised and the R&D tax incentive receipts for 2019 are insufficient to repay the principal and capitalised interest, the Group will enter into a new loan deed, on substantially the same terms, in respect of the balance of principal and accrued interest remaining, which will be repayable from the Group's R&D tax incentive receipts for 2020.

Other than the above, there are no matters or circumstances that have arisen since 31 December 2018 that have significantly affected or may significantly affect either the entity's operations in future financial years, the results of those operations in future financial years or the entity's state of affairs in future financial years.

### *Auditor's Independence Declaration*

A copy of the auditor's independence declaration, as required under Section 307C of the Corporations Act 2001, is included on page 6 of this report.

### *Rounding*

The amounts shown in this Financial Report, including the Directors' report, have been rounded off, except where otherwise stated, to the nearest dollar as the Company is in a class specified in ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191 dated 24 March 2016.

Signed in accordance with a resolution of the Board of Directors:



Roger Aston

Non-executive Chairman

28 February 2019



## 02 Auditor's Independence Declaration



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### Auditor's Independence Declaration

To the Directors of Regeneus Limited

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Regeneus Limited for the half-year ended 31 December 2018, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review;  
and
- b no contraventions of any applicable code of professional conduct in relation to the review.

A handwritten signature in black ink that reads "Grant Thornton".

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A handwritten signature in black ink that reads "L M Worsley".

L M Worsley  
Partner – Audit & Assurance

Sydney, 28<sup>th</sup> February 2019

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## 03 Consolidated Statement of Profit or Loss and Other Comprehensive Income

For the half-year ended 31 December	Note	31 Dec 18 \$	31 Dec 17 \$
Revenue		14,863	353,503
Cost of sales		-	-
Gross profit		14,863	353,503
Other income – R&D tax incentive	7	825,000	1,170,000
Research and development expenses		(1,298,949)	(2,133,411)
Occupancy expenses		(235,794)	(237,599)
Corporate expenses		(1,600,927)	(1,851,090)
Finance costs		(192,141)	(1,575)
Share of loss on investments accounted for using equity method		(16,512)	(13,596)
Unrealised foreign exchange loss on contract liability		(163,900)	-
Profit/(loss) before income tax		(2,668,360)	(2,713,768)
Income tax expense	8	-	-
Profit/(loss) for the period		(2,668,360)	(2,713,768)
Other comprehensive income		-	-
Total comprehensive profit/(loss) for the year		(2,668,360)	(2,713,768)
Earnings per share			
Basic earnings per share from continuing operations	9	(0.013)	(0.013)
Dilute earnings per share from continuing operations	9	(0.013)	(0.013)

Note: These financial statements should be read in conjunction with the accompanying notes.

## 03 Consolidated Statement of Financial Position

As at 31 December	Note	31 Dec 18 \$	30 Jun 18 \$
<b>Current Assets</b>			
Cash and cash equivalents		1,144,011	1,091,579
Trade and other receivables		-	-
Inventories		16,150	15,336
R&D tax incentive receivable		632,658	2,164,595
Other current assets		383,654	104,508
Financial asset at amortised cost		896,157	936,956
<b>Total current assets</b>		<b>3,072,630</b>	<b>4,312,974</b>
<b>Non-current assets</b>			
Property, plant and equipment		246,625	417,248
Intangible assets		1,104	1,644
Investments		26,873	41,263
Other non-current assets		-	210,000
<b>Total non-current assets</b>		<b>274,602</b>	<b>670,155</b>
<b>Total assets</b>		<b>3,347,232</b>	<b>4,983,129</b>
<b>Current liabilities</b>			
Trade and other payables		676,136	707,209
Provisions		103,034	111,398
Other current liabilities	12	1,880,000	1,000,000
Contract liabilities		3,548,050	-
<b>Total current liabilities</b>		<b>6,207,220</b>	<b>1,818,607</b>
<b>Non-current liabilities</b>			
Provisions		270,757	242,757
<b>Total non-current liabilities</b>		<b>270,757</b>	<b>242,757</b>
<b>Total liabilities</b>		<b>6,477,977</b>	<b>2,061,364</b>
<b>Net assets</b>		<b>(3,130,745)</b>	<b>2,921,765</b>
<b>Equity</b>			
Issued capital		31,076,819	31,076,819
Accumulated losses		(34,607,039)	(29,774,504)
Reserves		399,475	1,619,450
<b>Total equity</b>		<b>(3,130,745)</b>	<b>2,921,765</b>

Note: This statement should be read in conjunction with the notes to the financial statements

## 03 Consolidated Statement of Changes in Equity

For the half-year ended 31 December	Share capital \$	Share option reserve \$	Accumulated losses \$	Total attributable to parent owners \$	Total equity \$
Balance at 1 July 2017	31,076,819	1,652,773	(24,629,684)	8,099,908	8,099,908
Reported profit for the period	-	-	(2,713,768)	(2,713,768)	(2,713,768)
Employee share-based payment option expense	-	6,457	-	6,457	6,457
Transfer from reserves to retained earnings for options forfeited	-	-	-	-	-
Balance at 31 December 2017	31,076,819	1,659,230	(27,343,452)	5,392,597	5,392,597
Balance at 1 July 2018	31,076,819	1,619,450	(29,774,504)	2,921,765	2,921,765
Restatement for adoption of accounting standard AASB15	-	-	(3,384,150)	(3,384,150)	(3,384,150)
Restated balance at 1 July 2018	31,076,819	1,619,450	(33,158,654)	(462,385)	(462,385)
Reported loss for the period	-	-	(2,668,360)	(2,668,360)	(2,668,360)
Employee share-based payment option expense	-	-	-	-	-
Transfer from reserves to retained earnings for options forfeited	-	(1,219,975)	1,219,975	-	-
Balance at 31 December 2018	31,076,819	399,475	(34,607,039)	(3,130,745)	(3,130,745)

Note: This statement should be read in conjunction with the notes to the financial statements.

## 03 Consolidated Statement of Cash Flows

For the half-year ended 31 December	31 Dec 18 \$	31 Dec 17 \$
Operating activities		
Receipts from customers	-	339,015
Payments to suppliers and employees	(3,074,616)	(3,928,470)
Interest received	10,863	8,242
R&D tax incentive refund	2,356,937	2,608,223
Grant received	4,000	-
Finance costs	(121,062)	(1,575)
Net cash (used in)/provided by operating activities	(823,878)	(974,565)
Investing activities		
Payments for investments	-	-
Purchase of property, plant and equipment	(3,690)	(102,275)
Receipts from sale of property, plant and equipment	-	-
Net cash used in investing activities	(3,690)	(102,275)
Financing activities		
Receipts from loans to shareholders	-	313,650
Proceeds from related party loan	880,000	-
Net cash provided by financing activities	880,000	313,650
Net change in cash and cash equivalents held	52,432	(763,190)
Cash and cash equivalents at beginning of financial year	1,091,579	4,135,136
Cash and cash equivalents at end of financial year	1,144,011	3,371,946

Note: This statement should be read in conjunction with the notes to the financial statements.

# 04 Notes to the Consolidated Financial Statements

## 1. Nature of operations

Regeneus is a Sydney based ASX listed clinical stage regenerative medicine company that develops innovative cell-based therapies for human and animal health markets, with a focus on osteoarthritis, neuropathic pain and dermatology. The portfolio of therapeutic products is being developed using the Company's proprietary stem cell and immuno-oncology technology platforms.

Regenerative medicine is a rapidly growing multidisciplinary specialty that is focused on the repair or regeneration of cells, tissues and organs. The primary goal is to enhance the body's natural ability to replace tissue damaged or destroyed by injury or disease.

Where commercial opportunities are identified, the Group seeks to license appropriate parties.

## 2. General information and basis of preparation

The half-year consolidated financial statements of the Group are for the six months ended 31 December 2018 and are presented in Australian dollars (\$), which is the functional currency of the parent company.

These general purpose half-year financial statements have been prepared in accordance with the requirements of the Corporations Act 2001 and AASB 134 Interim Financial Reporting. They do not include all of the information required in annual financial statements in accordance with Australian Accounting Standards, and should be read in conjunction with the consolidated financial statements of the Group for the year ended 30 June 2018 and any public announcements made by the Group during the half-year in accordance with continuous disclosure requirements arising under the Australian Stock Exchange Listing Rules and the Corporations Act 2001.

The half-year financial statements have been approved and authorised for issue by the Board of Directors on 28 February 2019.

## 3. Going concern basis of accounting

For the half-year ended 31 December 2018, the Group generated a loss after income tax of \$2.7m (2017: \$2.7m), had net cash outflows from operating activities of \$0.8m (2017: \$1.0m); after taking into consideration the receipt of the R&D tax incentive of \$2.4m (2017: \$2.6m), and has a net deficiency of current assets of \$3.1m (30 June 2018: net current assets \$2.5m) after adjusting for the impact of the adoption of AASB 15 which resulted in the recognition of a contract liability of \$3.5m. The Group has a deficiency of net assets of \$3.1m (30 June 2018: net assets \$2.9m).

The Directors have prepared the financial statements on a going concern basis which contemplates continuity of normal activities and realisation of assets and settlement of liabilities in the normal course of business. In making their going concern assessment the Directors have considered the following:

- The near term opportunity as a listed company to raise additional capital at an appropriate time, which could include a private placement, possible rights issue or share purchase plan.
- The Directors had previously indicated that there were reasonable expectations that the Group would enter a clinical development and commercialisation licence with a Japanese marketing partner in the reporting period. It is now expected that such an arrangement will be achieved in the next 6 to 9 months. It is expected this licence will provide upfront funding and future payments contributing to the Group's funding requirements for the next 18 months.
- As noted above and as further discussed in note 5, the Group did not enter a clinical development and commercialisation licence with a Japanese marketing partner in the reporting period and therefore AGC Inc of Japan (AGC) are entitled to subscribe for USD \$2.5m of shares in Regeneus Limited and terminate the Manufacturing Licence Agreement and Shareholders Agreement ('the Agreements') in place or its intention to subscribe for shares. The Group to date has not received written notification of AGC's intention to terminate the Agreements, however, the Directors are working with AGC to resolve the status of the Agreements with AGC and expects to reach a resolution.
- After the reporting date, Directors provided an extension to the funding runway by entering into an unsecured loan agreement totaling \$2.5m which will be repayable on the earlier of 2 March 2020 or 10 days after a capital raise sufficient to fund repayment of the loans of the Company and support the working capital requirements of the Company for the following 12 months, as reasonably determined by the Board of Directors (Note 15).
- After the reporting date, Paddington St Finance amended the terms of its loan, such that all interest from 1 October 2018 will be accrued. The accrued interest and principal will be repayable from the Group's R&D tax incentive receipts for 2019 unless the Group has raised more than \$6 million from either a capital raise or the sale, licensing or other disposal of any of the Group's assets. Where \$6 million has not been raised and the R&D tax incentive receipts for 2019 are insufficient to repay the principal and capitalised interest, the Group will enter into a new loan deed, on substantially the same terms, in respect of the balance of principal and accrued interest remaining, which will be repayable from the Group's R&D tax incentive receipts for 2020. (Note 15);

## 04 Notes to the Consolidated Financial Statements

- The short term funding received on 28 February 2019 will enable the company to progress licensing discussions in Japan and review and prioritise other development programs and opportunities for Progenza and Sygenus;
- The Group has available to it and will consider, if necessary, cost reduction strategies.

Should the above transactions or assumptions not materialise, there is material uncertainty whether the consolidated entity will continue as a going concern and therefore whether it will realise its assets and extinguish its liabilities in the normal course of business and at the amounts stated in these financial statements.

### 4. Significant accounting policies

The half-year financial statements have been prepared in accordance with the same accounting policies adopted in the Group's last annual financial statements for the year ended 30 June 2018 with the exceptions of the following accounting standards, implemented in the reporting period.

#### Adoption of AASB 9: Financial instruments

This standard replaces AASB 139 Financial Instruments: Recognition and Measurement. AASB 9 includes revised guidance on the classification and measurement of financial instruments, including a new expected credit loss model for calculation of impairment on financial assets, and new general hedge accounting requirements. It also carries forward guidance on recognition and derecognition of financial instruments from AASB 139.

When adopting AASB 9, the Group has applied transitional relief and elected not to restate prior periods. Rather, differences arising from the adoption of AASB 9 in relation to classification, measurement, and impairment are recognised in opening retained earnings as at 1 July 2018.

On adoption of AASB 9, the Group has changed the accounting for impairment losses for financial assets and contract assets by replacing AASB 139's incurred loss approach with a forward-looking expected credit loss (ECL) approach, and has calculated ECLs based on the Group's historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment. No adjustment was raised upon initial adoption.

In addition, the adoption of AASB 9 has affected the classification of financial assets including the loans to shareholders \$936,956 being reclassified on 1 July 2018 from other current assets into financial assets held at amortised cost.

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding. After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments as well as loans to shareholders that were previously classified as held-to-maturity under AASB 139.

#### Adoption of AASB 15: Revenue from Contracts with Customers

AASB 15 establishes a comprehensive framework for determining whether, how much, and when revenue is recognised. It replaced AASB 118 Revenue and AASB 111 Construction Contracts and related interpretations. The Group has adopted AASB 15 from 1 July 2018 which resulted in changes in accounting policies, with no adjustments to amounts recognised in the half-year consolidated financial statements. In accordance with the transition provisions of AASB 15, the Group has adopted the modified retrospective transition approach, where any adjustment to historical revenue transactions (that impacts net profit) would be recorded against opening retained earnings as at 1 July 2018 and comparatives are not restated. The Group undertook a detailed review of its revenue contracts that were entered into during the transition period and concluded that an adjustment relating to the AGC Manufacturing Licence of \$3,384,150 (representing US\$2.5m translated at the spot rate on the date of transition) was required to the opening balances as a result of AASB 15 having a higher threshold in respect of constrained revenue than AASB 118.

For licence revenue, and in order to determine whether to recognise revenue, the Group follows a 5-step process: 1. Identifying the contract with a customer, 2. Identifying the performance obligations, 3. Determining the transaction price, 4. Allocating the transaction price to the performance obligations, 5. Recognising revenue when/as performance obligation(s) are satisfied.

The Group will enter into licence transactions and receive upfront and milestone payments as part of research and development collaborations or out-licensing agreements. The total transaction price for a contract is allocated amongst the various performance obligations based on their relative stand-alone selling prices using the residual method and cost method.

Revenue is recognised either at a point in time or over time, when (or as) the Group satisfies performance obligations by transferring the promised goods or services to its customers. The Group recognises contract liabilities for consideration received in respect of unsatisfied performance obligations or where revenue is constrained and reports these amounts as contract liabilities in the statement of financial position. Similarly, if the Group satisfies a performance obligation before it receives the consideration,

## 04 Notes to the Consolidated Financial Statements

the Group recognises either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

Licence revenue is determined with reference to performance obligations to provide either patents or IP. Licence revenues are considered a right to use and recognised at a point in time, net of any revenue constraints. All revenue is licence revenue.

The assessment of the criteria for income recognition and the determination of the appropriate period during which income is recognised are subject to judgement where variable consideration that is constrained and revenue is recognised only when it is highly probable that there will not be a significant reversal of revenue. The adjustment resulted in an increase in contract liability on initial recognition as follows:

	1 July 18 \$
Opening balance adjustment to initial recognition – accumulated losses	3,384,150
Contract liability recognised on initial recognition	3,384,150

### 5. Estimates

When preparing the half-year financial statements, management undertakes a number of judgements, estimates and assumptions about recognition and measurement of assets, liabilities, income and expenses. The actual results may differ from the judgements, estimates and assumptions made by management, and will seldom equal the estimated results.

The judgements, estimates and assumptions applied in the half-year financial statements, including the key sources of estimation uncertainty were the same as those applied in the Group's last annual financial statements for the year ended 30 June 2018 except as set out below:

#### Licence revenue

In December 2016 the Company entered into a Manufacturing Licence Agreement and Shareholders Agreement with AGC Inc of Japan (AGC). As part of these arrangements and in satisfaction of performance obligations the Company received an upfront payment and milestone payment totalling US\$6.5million. The Shareholders Agreement anticipated that AGC and Regeneus would work together to secure a marketing partner for the clinical development and commercialisation of Progenza in Japan. Furthermore, if securing such a partner was not achieved by 31 December 2018 then AGC had the opportunity to use US\$2.5million, paid as upfront and milestone payments, to subscribe for shares in Regeneus and to also cancel the arrangements. Throughout the intervening period from signing the agreements to 31 December 2018 both parties worked diligently to appoint a marketing partner and expected that it would be finalised within the period.

As set out in the 30 June 2018 annual report, Management determined that the Group had met the revenue criteria outlined in AASB 118 in respect of the milestone payments received during the prior year under the AGC Manufacturing Licence Agreement. As part of this assessment management made judgements relating to the probability of obtaining future milestone payments and the probability that any of the payments received to date may be subject to repayment or claw back provisions. On adoption of AASB 15 Management determined that an adjustment of \$3,384,150 (representing US\$2.5m translated at the spot rate on the date of transition) was required to the opening balances as a result of AASB 15 having a higher threshold in respect of constrained revenue than AASB 118.

As at 31 December 2018, while ongoing negotiations are progressing well, a marketing partner has not been appointed. AGC has not taken the requisite steps to invoke the necessary clauses in the agreements. Should AGC invoke the relevant clauses in the Agreements, the contract liability would be settled in shares. As at 31 December 2018 the potential share subscription was equivalent to 19,711,388 shares at \$0.18 totalling \$3,548,050. These shares remain unissued at the date of this report.

#### Loans to Shareholder

The Group holds full recourse loans to shareholders totalling \$896,157 that were provided at the time of the 2013 IPO. As outlined above, the Group has not made an adjustment for expected credit losses. The Group assesses expected credit losses with reference to the history of losses and considering the value of shares held by the shareholders to determine future expected credit losses. No provision for expected credit losses has been raised against the loans to shareholders, however, subsequent to reporting date the share price has reduced. The reduction in share price to 0.10 on 26 February 2019 prima facie could result in an expected credit loss of circa \$215,000.

### 6. Segment reporting

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers (CODM). The CODM is responsible for the allocation of resources to operating segments and assessing their performance.



## 04 Notes to the Consolidated Financial Statements

The Group's operating segment is based on the internal reports that are reviewed and used by the Board of Directors (being the CODM) in assessing performance and in determining the allocation of resources. Reports provided to the CODM reference the Group operating in one segment, being the development of innovative cell-based therapies to address significant unmet medical needs in human and animal health. Initial focus is osteoarthritis and other musculoskeletal disease as well as oncology and dermatology. The information reported to the CODM, on a monthly basis, is profit or loss before tax, assets and liabilities and cash flow.

### 7. Other income – R&D tax incentive

The Group's research and development activities are eligible expenditure under the Australian Government tax incentive program. Under this program the government provides a cash refund for 43.5% (2017: 43.5%) of eligible research and development expenditures.

For the 6 month period ended 31 December 2018, the Group estimated the R&D tax incentive income receivable following the lodgement of the 2019 tax return to be \$0.8m (2017: \$1.2m). The Group has confidence about the quantum of expenditure at the half year which will qualify under the program and confidence in its internal systems and processes in order to enable it to reliably measure the eligible R&D expenditure at the 31 December 2018 half year.

	31 Dec 18 \$	31 Dec 17 \$
R&D tax incentive	825,000	1,170,000
Other income	825,000	1,170,000

### 8. Income tax expense

No income tax expense or liability has been recognised in the half-year accounts as the Group has available unused tax losses as at 30 June 2018 of \$5,119,801 (30 June 2017: \$3,143,290) which have not previously been brought to account.

### 9. Earnings per share

Both the basic and diluted earnings per share have been calculated using the profit attributable to shareholders of the parent company (Regeneus Ltd) as the numerator, i.e. no adjustments to profits were necessary during the six month period to 31 December 2018 and 31 December 2017.

The weighted average number of shares for the purposes of the calculation of diluted earnings per share can be reconciled to the weighted average number of ordinary shares used in the calculation of basic earnings per share as follows:

	31 Dec 18 \$	31 Dec 17 \$
Basic earnings per share from continuing operations	(0.013)	(0.013)
The weighted average number of ordinary shares used as the denominator on calculating the EPS	208,885,143	208,885,143
Diluted earnings per share		
Basic earnings per share from continuing operations	(0.013)	(0.013)
The weighted average number of ordinary shares used as the denominator on calculating the DEPS	208,885,143	208,885,143

At 31 December 2018 share options are not included in the diluted EPS calculation because they are anti-dilutive. (2017: nil)

### 10. Share capital

The share capital of Regeneus Ltd consists only of fully paid ordinary shares; the shares do not have a par value. All shares are equally eligible to receive dividends and the repayment of capital and represent one vote at the shareholders' meeting of Regeneus Ltd.

During the six months to 31 December 2018, there were no shares issued. During the prior comparable period no shares were issued.

## 04 Notes to the Consolidated Financial Statements

Shares issued and authorised are summarised as follows:

Share Capital	31 Dec 18 \$	30 Jun 18 \$
Fully paid shares	31,076,819	31,076,819
	<b>31,076,819</b>	<b>31,076,819</b>

The company has 3,171,774 options on issue to acquire ordinary shares in the company. These options are unlisted, restricted and summarised as follows:

Share options	31 Dec 18 Number	30 Jun 18 Number
Employee share option plans	3,171,774	9,159,984
	<b>3,171,774</b>	<b>9,159,984</b>

### 11. Share-based payments

The grant date fair value of options granted to employees is recognised as an employee benefit expense, with a corresponding increase in equity within the shares options reserve. The amount recognised is adjusted to reflect actual number of the share options vested.

All share-based remuneration will be settled in equity. The Group has no legal or constructive obligation to repurchase or settle the options.

The fair value of share options was calculated using a binomial options pricing model. For the options outstanding at period end, the following inputs were used:

Grant date	1 Jul 2010	21 Feb 2011	1 Jul 2011	21 Nov 2014
Share price at date of grant	\$0.136	\$0.136	\$0.280	\$0.160
Volatility	45%	45%	45%	244%
Option life	10 years	10 years	10 years	5 years
Dividend yield	0%	0%	0%	0%
Risk free investment rate	5.10%	5.60%	5.30%	2.80%
Fair value at grant date	\$0.085	\$0.085	\$0.180	\$0.179
Exercise price at date of grant	\$0.136	\$0.136	\$0.280	\$0.160

Employee benefits expenses in the profit or loss includes \$nil relating to employee share options (Dec 2017: \$6,457).

Share options granted under the option plans	31 Dec 18		30 Jun 18	
	Number	Weighted avg exercise price \$	Number	Weighted avg exercise price \$
Options outstanding at beginning of period	9,159,984	0.22	9,622,044	0.22
Forfeited	(5,988,210)	0.25	(462,060)	0.14
Outstanding at end of period	3,171,774	0.17	9,159,984	0.22
Exercisable at end of period	3,171,774	0.17	9,159,984	0.22

Options forfeited predominantly related to share options previously granted to eligible participants. Expiration of the options or cessation of employment or contract has resulted in these options no longer being exercisable.

### 12. Related party transactions

On 29 June 2018, the Company entered into an R&D loan facility agreement with Paddington St Finance Pty Ltd, a related party. The facility forward funded, via a loan, the lesser of 80% of the expected R&D claim or \$2m. During the reporting period the amount drawn down was increased to \$1.88m from 30 June 2018 \$1.00m.

## 04 Notes to the Consolidated Financial Statements

On August 27 2018, the Board of Directors renegotiated the payment terms of the loan to Paddington St Finance Pty Ltd. Paddington St Finance agreed to defer the repayment of the loan to the earlier of receipt of the next milestone payment under the manufacturing licence with AGC Inc; the receipt of the FY19 R&D Tax Incentive; and 30 September 2019.

Related party loan payable	31 Dec 18 \$	31 Dec 17 \$
Paddington St Finance Pty Ltd	1,880,000	-
<b>Total related parties loans</b>	<b>1,880,000</b>	<b>-</b>

At the time of the IPO in August 2013, the Company provided loans to shareholders in connection with the funding of the exercise of employee options. The loans are full recourse interest-free loans for 4 years, with maturity extended to June 2019. Included within the loans to shareholders in other current assets, are balances owing by the Directors as follows:

Related party loan receivable	31 Dec 18 \$	31 Dec 17 \$
John Martin	295,925	295,925
Graham Vesey	150,552	150,552
<b>Total related parties loans</b>	<b>446,477</b>	<b>446,477</b>

### 13. Dividends

No dividends were paid during the period (2017: \$nil).

### 14. Contingent liabilities

The group had no contingent liabilities as at 31 December 2018 (31 December 2017: Nil).

### 15. Events after the reporting date

In the period since 31 December 2018 to the signing of the financial report, the following significant events have occurred:

On the 23 January, Leo Lee, formerly a non-executive Director was appointed, pending shareholder approval, to the position of Managing Director and CEO. John Martin resigned as CEO and will remain on the Board as a Non-executive Director.

On the 28 February 2019, the Company received loans from the Directors in total of \$2,500,000. Regeneus had previously considered funding from other sources and determined these Director loans were the most attractive commercial arrangement and entered into the necessary arrangement on arm's length terms. The loans are unsecured and repayable on the earlier of 2 March 2020 or 10 days after a capital raise sufficient to fund repayment of the loans of the Company and support the working capital requirements of the Company for the following 12 months as reasonably determined by the Board of Directors.

Also, at that time Paddington St Finance amended the terms of its loan such that all interest from 1 October 2018 will be accrued. The accrued interest and principal will be repayable from the Group's R&D tax incentive receipts for 2019 unless the Group has raised more than \$6 million from either a capital raise or the sale, licensing or other disposal of any of the Group's assets. Where \$6 million has not been raised and the R&D tax incentive receipts for 2019 are insufficient to repay the principal and capitalised interest, the Group will enter into a new loan deed, on substantially the same terms, in respect of the balance of principal and accrued interest remaining, which will be repayable from the Group's R&D tax incentive receipts for 2020.

Other than the above, there are no matters or circumstances that have arisen since 31 December 2018 that have significantly affected or may significantly affect either the entity's operations in future financial years, the results of those operations in future financial years or the entity's state of affairs in future financial years.

## 05 Director's Declaration

### Directors' declaration

1. In the opinion of the Directors of Regeneus Ltd:

- a. the consolidated financial statements and notes of Regeneus Ltd are in accordance with the Corporations Act 2001, including:
  - i) giving a true and fair view of its financial position as at 31 December 2018 and of its performance for the half-year ended on that date; and
  - ii) complying with Accounting Standard AASB 134 Interim Financial Reporting; and
- b. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Board of Directors:



Non-executive Chairman

Roger Aston

Dated 28 February 2019



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## Independent Auditor's Review Report

To the Members of Regeneus Limited

Report on the review of the half-year financial report

### Conclusion

We have reviewed the accompanying half-year financial report of Regeneus Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2018, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the half-year financial report of Regeneus Limited does not give a true and fair view of the financial position of the Group as at 31 December 2018, and of its financial performance and its cash flows for the half-year ended on that date, in accordance with the *Corporations Act 2001*, including complying with Accounting Standard AASB 134 *Interim Financial Reporting*.

### Material uncertainty related to going concern

We draw attention to Note 3 to the financial report which describes material uncertainties related to Regeneus Limited's ability to continue as a going concern.

These conditions, along with other matters as set forth in Note 3, indicate the existence of a material uncertainty which may cast significant doubt about the Group's ability to continue as a going concern and therefore, the Group may be unable to realise its assets and discharge its liabilities in the normal course of business, and at the amounts stated in the financial report.

Our report is not modified in relation to this matter.

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### Directors' responsibility for the half year financial report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2018 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Regeneus Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

A stylized, handwritten signature of "Grant Thornton" in black ink.

Grant Thornton Audit Pty Ltd  
Chartered Accountants

A stylized, handwritten signature of "L M Worsley" in black ink.

L M Worsley  
Partner – Audit & Assurance

Sydney, 28<sup>th</sup> February 2019

### Registered Office and Principal Place of Business

25 Bridge Street  
Pymble, NSW 2073, Australia

### Board of Directors

Dr. Roger Aston (Non-executive Chairman)  
Leo Lee (Executive Director)  
Professor Graham Vesey (Executive Director)  
Barry Sechos (Non-executive Director)  
Dr. Glen Richards (Non-executive Director)  
John Martin (Non-executive Director)

### Company Secretary

Sandra McIntosh

### Website

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### Auditors

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### Patent Attorneys

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### Share Registry

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### Stock Exchange Listing

Australian Stock Exchange  
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